

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: ALL CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION FOR ENTRY OF A
PROTECTIVE ORDER AND TO QUASH PLAINTIFFS' 30(b)(6) DEPOSITION
NOTICE**

Defendants seek to quash Plaintiff's 30(b)(6) deposition notice on 23 topics intended to discover potential manufacturing defect issues related to the pelvic mesh products. Defendants attempt to characterize this notice and all 23 topics in this notice as relating to the issue of particle loss, but they do not. The focus of this 30(b)(6) notice is the manufacturing processes, facilities, and equipment used to cut, sterilize, and package the TVT. Foreign matter in the product and packaging is only one issue that can arise during the manufacturing process, including mesh particle loss, metal particles, hairs, or other foreign matter in the product or packaging. Moreover, defendants' motion to quash this notice should be denied as the notice is not duplicative of prior testimony. There have been thousands of new documents produced and new manufacturing issues identified since Plaintiffs have last had an opportunity to depose an Ethicon 30(b)(6) witness, or a relevant Ethicon fact witness.

Most depositions of Ethicon witnesses occurred on or before February 2, 2014. Only seven MDL depositions of Ethicon corporate witnesses have occurred after that date, and only

one of those witnesses was a 30(b)(6) witness. That witness was designated on limited topics of certain payments made by Ethicon and Johnson & Johnson to medical societies and the inventors of the TVT-O. Ethicon Sarl (Neuchatel, Switzerland) is the legal manufacturer of the TVT products. However, at this point, Plaintiffs have yet to depose a single employee who works at the Ethicon Sarl manufacturing facility, or a single person who is directly involved in the actual manufacturing of the TVT products. Since February 2, 2014, Defendants have produced more than 1 million pages of new documents. Three of the seven documents attached to the deposition notice were not produced until **after** February 2, 2014, when Ethicon's last design defect 30(b)(6) witness was deposed, a fact which was communicated to defense counsel. (*See* Letter from Andrew Faes to Phil Combs, Sept. 23, 2015, attached as Ex. B-1).¹

Exhibit A-1 to the notice depicts returned products from seven different lots of TVT-O production in Neuchatel. The issue of these returned products, and the manufacturing issues which resulted in their return to Ethicon, are particularly pertinent and timely. A TVT-O from one of these lots, Lot 3405428, was implanted in a plaintiff whose case is set for trial on January 11, 2016 in the 438th Judicial District of Bexar County, Texas.² Lot 3405428 produced only 993 TVT-O's. In addition, Plaintiffs have determined that for six of the seven lot numbers included in the returned products depicted in Exhibit A-1, there is at least one Plaintiff with a case on file

¹ Exhibit A-1 to the 30(b)(6) notice was produced to Plaintiffs on 02/28/2014. Exhibit A-5 on 02/28/2014, and Exhibit A-6 on 04/01/2014. Notably, the defendants claim that six of seven exhibits to the current 30(b)(6) notice were produced prior to the deposition of Dan Lamont on September 11, 2013. (*See* defendant's motion at page 5). As the above production dates indicate, this assertion is false. Moreover, exhibit A-1, which contains photographs of the returned product were not produced until February of 2014. While there were documents discussing the returned product that were available and used at Mr. Lamont's deposition, Plaintiffs did not have the benefit of having a visual depiction of the products at issue, or the benefit of knowing that there was a manufacturing issue which resulted in nearly 2,000 products being discarded at Ethicon Neuchatel due to particles AND foreign material in product and packaging (*See* Exhibit B-4, attached hereto, which is a certified translation of exhibit A-6 to the original 30(b)(6) notice. Having actual photographs of the product issue is quite different from discussing the returned product in the abstract, and without the benefit of being aware of a systemic problem, that appears to have resulted in the discarding of thousands of products.

² This case is *Jennifer Ramirez v. Ethicon, Inc. et. al.*, which was recently remanded for trial by this court.

who was implanted with a product from those lots.³ Plaintiffs have also discovered, through recently produced documents, that there may be far more TVT lots affected by this issue, which resulted in the shutdown of the entire TVT production line and the apparent discarding of thousands of mesh products.

ARGUMENT

A. The federal rules provide for extremely broad discovery.

Under Federal Rule of Civil Procedure 26(b)(1), parties are entitled to “discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense.” The information sought does not, itself, need to be admissible evidence. Rather, parties are entitled to discover any information that “appears reasonably calculated to lead to the discovery of admissible evidence.” *Id.* “The purpose of discovery is to allow a broad search for facts, the names of witnesses, or any other matters which may aid a party in the preparation or presentation of his case.” *Id.*, advisory committee notes to 1946 amendments (emphasis added).

Courts have long held that the federal discovery rules “are to be accorded a broad and liberal treatment.” *Ralston Purina Co. v. McFarland*, 550 F.2d 967, 973 (4th Cir. 1977), *quoting Hickman v. Taylor*, 329 U.S. 495, 507 (1947). “No longer can the time-honored cry of ‘fishing expedition’ serve to preclude a party from inquiring into the facts underlying his opponent’s case.” *Id.* A party seeking to restrict or inhibit discovery has “the burden of demonstrating the need for protection.” *Wood v. Harshbarger*, No. 3:13-cv-21079, 2014 WL 3056855, at *2 (S.D. W. Va. July 7, 2014) (Eifert, Mag. J.). “To prevail on the grounds of burdensomeness,

³ There were seven lot numbers associated with the returned TVT-O product: 3405428, 34133118, 3398077, 3413119, 3413121, 3389752, 3389753. 3405428: Jennifer Ramirez, 2012-CI-18690 (Bexar County, TX); 3413118: Lorraine Barton, case 2013-04941 (NJ consolidation); 3398077: Diana Marie Mitchell, 2012-07469; 3413119: Frankie Johnson, 2013-00965 (Philadelphia consolidation); 3413121, Ignacia Sandoval, 2014-17638; 3389752: Janice Oaks, 2014-02132.

oppression, or breadth, the opposing party must do more to carry its burden than simply make conclusory and unsubstantiated arguments.” *Id.*

I. PLAINTIFFS SHOULD BE ALLOWED TO DISCOVER ADDITIONAL TESTIMONY ON MANUFACTURING ISSUES RELATED TO THE TVT

The focus of the current 30(b)(6) notice is the manufacturing processes, facilities, and equipment used to cut, sterilize, and package the TVT, not particle loss as the defendants assert in their motion to quash. This has been made clear in correspondence to Defense counsel. In fact, Plaintiffs requested an initial listing of manufacturing documents needed to address the topics in the notice, including but not limited to documentation regarding the facilities, equipment, procedures, and forms used to cut, sterilize, and package the TVT products. (*See* letter from Andrew Faes to Christy Jones, July 17, 2015, page 5, attached as Ex. B-2). In addition, Plaintiffs have recently discovered that in March 2010, the TVT production line was completely shut down due to metallic particles (burrs) being discovered in the TVT packaging. (*See* e-mail from Perrine Hibon, March 17, 2010, attached as ex. B-3).⁴ This production line shut-down occurred approximately 10 days after the products depicted in exhibit A-1 of Plaintiffs’ deposition notice were manufactured on this line. These dates coincide with documentation indicating that nearly 2,000 products were rejected by Ethicon’s Neuchatel manufacturing facility in March of 2010. (*See* e-mail from Jamil Jaccard, August 17, 2010 and attached power point, attached as ex. B-4).⁵ Documents indicate that these issues continued well into 2013. (*See* CAPA #130022- repetition of NCR for particles, attached as Exs. B-5, B-6, B-7).⁶ Documents indicate that this problem continued through 2014, when the implementation of

⁴ This document, ETH.MESH.13906093 was not produced to Plaintiff until 04/01/2014, which was after the majority of Ethicon witnesses were deposed.

⁵ This document, at ETH.MESH.13907354-13907355, was not produced until 04/01/2014.

⁶ These documents, ETH.MESH.15137986, ETH.MESH.15137980, ETH.MESH.15137979, were not produced to plaintiffs until 05/22/2014.

a new sheath holder on the production line was installed, reducing the number of impacted batches from 10.8% to 0.25%. (*See* MDD CAPA database export, attached as Ex. B-8).⁷ To this date, there has been no substantive discovery of metallic particles in product and packaging, the shutdown of the TVT standard production line in March of 2010, the rejection of nearly 2,000 products made in the Neuchatel manufacturing facility during the same month, or the change to the TVT manufacturing process made as a result of these issues. Plaintiffs were not provided with documentation on these subjects until the majority of corporate depositions had been completed. The documents and issues discussed here represent merely a sampling of the newly produced documents and subjects Plaintiffs intend to discover, which are more fully set out in Plaintiff's 30(b)(6) notice and document requests.

II. THE COURT SHOULD NOT BAR ADDITIONAL TESTIMONY ON THE ISSUE OF PARTICLE LOSS AS THERE HAVE BEEN NEW DOCUMENTS AND ISSUES DISCOVERED SINCE DEFENDANTS' DESIGNEES AND WITNESSES WERE LAST DEPOSED.

Even if the court accepts the Defendants' mistaken premise that the 23 topics in Plaintiffs' 30(b)(6) notice are all related to particle loss, it is incorrect to conclude that Plaintiffs have already had an adequate opportunity to discover this topic. Plaintiffs did not have the majority of documents responsive to this notice prior to the depositions cited in Exhibit 1 of Defendants' motion to quash. Plaintiffs' manufacturing 30(b)(6) notice included 18 document requests directly related to the 23 topics in the notice. In response to these 18 requests, Defendants identified 297 responsive documents. (*See* Letter from Rich Bernardo to Andrew Faes, October 6, 2015, attached as Ex. B-9). Plaintiffs have analyzed the production dates of these 297 documents, and 180 (more than 60%) were produced after February 2, 2014—the last day Ethicon produced a 30(b)(6) designee on any topics related to the subjects in the current

⁷ This document, ETH.MESH.15137959, was not produced to plaintiffs until 05/22/2014

notice. (*See* production dates for documents identified by defendants in October 6, 2015 letter responding to 30(b)(6) document requests, attached as Ex. B-10). In addition, only seven Ethicon corporate witnesses have been deposed in the MDL since February 2, 2014. Defendants' assertion that Plaintiffs have already had ample opportunity to discover this topic is illogical because Plaintiffs did not have even half of the documents related to the topics in the notice at the time of the previous depositions.

For instance, Defendants cite the testimony of medical director Piet Hinoul for the proposition that there is no evidence that particle loss raises a clinical concern, and that this topic has already been adequately addressed. (*See* Defendants' motion at 5.) However, newly produced documents indicate that Ethicon engineers performed risk assessments which indicated that particles and foreign material in products and packaging could potentially raise a clinical concern. These risk assessments indicate that particles and foreign material may result in bio-contamination, infection, inflammation or other unintended tissue reaction, and failure of treatment. (*See* defect to harms maps, attached as Exs. B-11, B-12).⁸ As these documents were not produced to Plaintiffs until after Dr. Hinoul was last deposed on January 15, 2014, Plaintiffs have not had an opportunity to cross-examine Dr. Hinoul, or any of Ethicon's other 30(b)(6) designees, on these documents. This is a single example, but there are surely many more in the 180 new documents Defendants identified as responsive to Plaintiffs' document requests, and the millions of pages of other documents which have been newly produced.

At the very least, Plaintiffs need to have Ethicon produce a designee on exhibits A-1, A-5, and A-6 to the notice, as they were not produced until after the majority of Ethicon corporate witnesses were deposed, were produced after all 30(b)(6) witness were deposed, and have not

⁸ Exhibit B-11, at ETH.MESH.22680210, was not produced until 08/17/2015. Exhibit B-12 at ETH.MESH.22852060, was not produced until 10/05/2015.

been previously used with any Ethicon witness. The need is particularly acute, given that the aforementioned Ramirez case is set for trial, and the defendants routinely raise foundation objections at trial to the admission of documents where the witness has no personal knowledge of the document(s).

Plaintiffs anticipate that when confronted with the evidence that the majority of documents identified as responsive to Plaintiffs' document requests in this notice were recently produced, Defendants may alternatively request that the court restrict questioning to newly produced documents only. The Court should reject any such argument. Documents A-1, A-5, and A-6 to the original notice were clearly in existence in 2010, and could have been produced prior to the various 30(b)(6) depositions that occurred in 2013. Defendants should not profit from their late production of these documents. Moreover, limiting Plaintiffs to only the newly produced documents would be akin to providing the Plaintiffs with a few dozen pieces to a thousand piece jigsaw puzzle in 2012, and then providing the remaining pieces in 2014, while seeking to limit examination on the earlier produced pieces. This is also unfair. Plaintiffs could not ask the proper questions about the earlier documents without knowing what the completed puzzle looked like. Plaintiffs will certainly agree that the focus of their examination will be on the newly produced documents but cannot agree to completely exclude earlier produced documents.

III. PLAINTIFFS DEPOSITION NOTICE IS NOT OVERBROAD AND UNDULY BURDENSOME, AND IN FACT, IS MORE EFFICIENT THAN ALTERNATIVE FORMS OF DISCOVERY.

The current deposition notice is not overly broad and, in fact, is more efficient and less burdensome than alternate forms of discovery. Though several Ethicon corporate witnesses have been deposed, Plaintiffs have yet to depose a single employee who works at Ethicon Sarl (the

legal manufacturer of TVT, located in Neuchatel), or a single individual who is directly involved in the manufacturing of the TVT products. As discussed in Section I, there are now a number of recently produced documents which indicate a potential systemic manufacturing defect or defects with the TVT, which have not previously been the subject of discovery or depositions. Certainly, the benefit of this discovery is not minimal or insignificant to those Plaintiffs who were implanted with products manufactured while these issues occurred. To accomplish the goal of depositing an appropriate witness who has personal knowledge of the documents and subjects in the notice, **and** the ability to lay a foundation for the newly produced documents and topics the Plaintiffs now need to discover, Plaintiffs would need to depose at least a dozen individuals, most of whom reside or work in Neuchatel, Switzerland, or countries other than the United States, and likely do not speak English as their primary language.⁹ Plaintiffs believe that by laying out a single 30(b)(6) notice and providing Defendants with the exact topics on which discovery is sought, they are making the most efficient use of everyone's resources.

In conclusion, Plaintiffs have not deposed a single employee of Ethicon's Neuchatel, Switzerland manufacturing facility, or a single witness on the manufacturing issues which resulted in the shutdown of the TVT standard line and the rejection of nearly 2,000 products in 2010. Defendants' own response to Plaintiffs' documents request attached to the 30(b)(6) notice belie their argument that Plaintiffs have already had sufficient opportunity to examine witnesses on the topics in the notice, as greater than 60% of the documents identified were produced after all but seven of Ethicon's corporate witnesses were deposed. There is not a single document

⁹ In order to establish foundation and personal knowledge of the documents and subjects in the notice, Plaintiffs would need to depose: Kathie Chen, Jamil Jaccard, Claire Heron, Stephane Poulot, Karine Hostache, Atimad El Fettouhi, Vincent Journot, Ed Jacobs, Dan Smith, Anthony Lamouille, Jeff Meltzer, Dan Smith, and Marty Weisberg. The majority of these witnesses live outside of the United States and do not speak English as a primary language.

request or deposition topic in the notice where all of the documents responsive to the request were available at the time of the previous depositions.

CONCLUSION

For all of the reasons set forth above, Plaintiffs respectfully request that the Court deny Defendants' motion for protective order and to quash plaintiffs' 30(b)(6) notice.

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CERTIFICATE OF SERVICE

I hereby certify that on October 27, 2015, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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